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09/691,155	10/19/2000	Robert A. Hoffman	P-4744	4567

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EXAMINER

GEISEL, KARA E

ART UNIT

PAPER NUMBER

2877

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/691,155

Applicant(s)

HOFFMAN ET AL.

Examiner

Kara E Geisel

Art Unit

2877

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-12,14-18 and 21-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 is/are allowed.
- 6) ☒ Claim(s) 1-4,7-12,14-18,21-25,27-40 and 42-51 is/are rejected.
- 7) ☒ Claim(s) 41 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed on March 27, 2003 has been fully considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-33 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Zarling et al. (USPN 5,674,698), newly cited.

In regards to claims 31 and 43, Zarling discloses an apparatus that can be used for examining a particle in a flow stream of a flow cytometer (column 7-8, lines 65-67 and 1-7, respectively) comprising a light emitting device which can comprise at least one light emitting diode (fig. 3, 20(1) and column 33, lines 52-55) adapted to emit light toward a flow stream, a detector (fig. 3, 22(1)) adapted to detect light emanating from said particle (fig. 3, 15) in response to said emitted light striking said particle (column 33, lines 52-67), and a controller (fig. 3, 50) adapted to control said light emitting device to emit light in pulses (column 35, lines 36-41).

In regards to claims 32 and 44, the emanating light comprises fluorescent light and the detector is adapted to detect said fluorescent light (column 12, lines 37-54).

In regards to claims 33 and 45, the light emitting device comprises two incoherent light emitting semiconductor devices (fig. 1, 20(1) and 20(2)) each adapted to emit a respective light toward said flow

Art Unit: 2877

stream and the detector (fig. 1, 22(1) and 22(2)) is adapted to detect each light emanating from said particle in response to said respective emitted lights (column 33, lines 39-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 7-10, 15-17, 21-24, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (USPN 5,563,070), previously cited, in view of Kusuzawa (USPN 5,596,401) previously cited, and further in view of Marzari et al. (USPN 4,800,265), newly cited.

In regards to claims 1, 7-10, 15, and 21-24, Yamamoto discloses an apparatus for examining a particle in a flow stream of a flow cytometer (fig. 13) comprising a light emitting device (fig. 13, 15) comprising one incoherent light emitting semiconductor device (column 6, lines 52-55 and 58-61; column 8, lines 21-23) adapted to emit light toward the flow stream (column 9, lines 50-53), and a detector (fig. 13, 17) adapted to detect light emanating from the particle in response to emitted light striking the particle (column 9, lines 50-53). Yamamoto does not disclose a second system for detecting the particle so that

Art Unit: 2877

the first system can analyze the particle. However, this is well known in the art, and it would have been obvious to a person of ordinary skill in the art to add a second detection system in order to detect the particle, and control the first light source to image the particle once it has been detected.

For example, Kusuzawa discloses an apparatus for examining a particle in a flow stream of a flow cytometer. The apparatus includes a controller (fig. 1, 26) adapted to control the light-emitting device to emit light for a predetermined period, during which the emitted light radiates on the particle (column 8, lines 8-13). This controller is adapted to control the light-emitting device to emit light in pulses (column 5, lines 11-18). The apparatus further includes a second substantially coherent light-emitting device adapted to emit its light towards the flow stream (fig. 1, 8), which is a laser (column 7, lines 56-67 and column 8, lines 1-13). There is a second detector (fig. 1, 20 and 22) adapted to detect the second light emanating from the particle in response to the second emitted light striking the particle (column 7, 62-67). The controller is adapted to control the first light emitting device based on the detection of the second emanating light by the second detector (column 8, lines 8-17).

Neither reference teaches the controlling the light-emitting device to emit light having a duty cycle less than about 10%. However, it is very well known in the art to control a light-emitting device to have a duty cycle less than 10% in order to increase the life of the LED and battery, and increase the intensity of the light pulse.

For example, Marzari teaches pulsing a LED with a duty cycle of less than 10% (column 3, lines 40-44). This is in order to reduce power consumption and to lengthen battery life of the system (column 3, lines 40-57). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to pulse the light-emitting device of the combined system with a duty cycle less than about 10% in order to reduce power consumption.

In regards to claims 2, 16, 27, and 29 the apparatus for examining a particle in a flow stream of a flow cytometer is discussed above. Furthermore, the incoherent light emitting semiconductor device

Art Unit: 2877

(Yamamoto fig. 13, 15) is a light emitting diode (Yamamoto column 6 lines 52-61 and column 8, lines 21-23).

In regards to claims 3 and 17, the apparatus for examining a particle in a flow stream of a flow cytometer is discussed above. Furthermore, the emanating light comprises fluorescent light and the detector is adapted to detect fluorescent light (Yamamoto column 9, lines 46-55).

Claims 4, 18, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (USPN 5,563,070) previously cited, in view of Kusuzawa (USPN 5,596,401), previously cited, further in view of Marzari et al. (USPN 4,800,265), newly cited, and further in view of Unterleitner (USPN 4,498,766), previously cited.

In regards to claims 4 and 18, the combined apparatus for examining a particle in a flow stream of a flow cytometer is discussed above. The combined system does not disclose two incoherent light emitting semiconductor devices.

Unterleitner discloses a flow cytometer with two exciting light sources (fig. 1, 14 and 12), which may be incoherent (column 4, lines 2-6). Two incoherent exciting light sources of different wavelengths are used so that it is possible to detect and monitor two different types of particles having different fluorescent characteristics (column 3, lines 42-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add another incoherent light emitting semiconductor device with a respective light emission to Yamamoto's flow cytometer and furthermore adapt the detectors to detect each light emanating from a particle in response to each emitted light in order to detect and monitor two different types of fluorescing particles.

In regards to claims 28 and 30, apparatus for examining a particle in a flow stream of a flow cytometer is discussed above. The combined system does not disclose having the LED emit light in the ultraviolet range. However, it is well known in the art that some markers need UV light to fluoresce, and

Art Unit: 2877

it would be obvious to one of ordinary skill at the time the invention was made to use an ultraviolet LED in order to fluoresce these markers.

For example, Unterleitner discloses using an ultraviolet light source, which could be an incoherent light source such as an LED, in a flow cytometry apparatus in order to excite fluorochromes to fluoresce (columns 3-4, lines 58-68 and 1-6, respectively). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the LED emit ultraviolet light in order to be able to use a fluorochrome that excites by UV radiation.

Claims 11-12, 14, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (USPN 5,563,070) previously cited, in view of Kusuzawa (USPN 5,596,401), previously cited, further in view of Marzari et al. (USPN 4,800,265), newly cited, and further in view of Hoffman et al. (USPN 5,528,045), previously cited.

In regards to claims 11-12 and 25, the combined apparatus for examining a particle in a flow stream of a flow cytometer is discussed above. The combined system does not disclose a light-obstructing device with two transparent portions to allow portions of the emanating light from a particle to be detected.

Hoffman discloses an apparatus for detecting particles in a flow cytometer. The particles are tagged with multiple fluorochromes, which are excited at different locations in a flow cell by different excitation sources. A light-obstructing device (fig. 1, SPF), having a substantially opaque portion and two substantially transparent portions (Fig. 1, AP1 and AP2), is placed before a detector so that the emanating light from each fluorochrome attached to the particle can be discriminated and detected separately (column 2, lines 49-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a light obstructing device with two substantially transparent portions into Yamamoto's apparatus in order to detect light from two different fluorochromes attached to a particle.

In regards to claim 14, combining a light-obstructing device with an apparatus for examining a particle in a flow stream of a flow cytometer is discussed above. Furthermore, the light-obstructing device is located at an image plane (Hoffman column 3, lines 1-5).

Claims 34-38 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zarling et al. (USPN 5,674,698), newly cited, in view of Kusuzawa (USPN 5,596,401), previously cited.

In regards to claims 34-38 and 46-50, Zarling discloses an apparatus for examining a particle in a flow stream of a flow cytometer as discussed above. Zarling does not disclose a second system for detecting the particle before the particle is analyzed. However, a second system for detecting a particle so that the first system can analyze the particle is well known in the art, and it would have been obvious to a person of ordinary skill in the art to add a second detection system in order to detect the particle, and control the first light source to image the particle once it has been detected.

For example, Kusuzawa discloses an apparatus for examining a particle in a flow stream of a flow cytometer. The apparatus includes a controller (fig. 1, 26) adapted to control the light-emitting device to emit light for a predetermined period, during which the emitted light radiates on the particle (column 8, lines 8-13). This controller is adapted to control the light-emitting device to emit light in pulses (column 5, lines 11-18). The apparatus further includes a second substantially coherent light-emitting device adapted to emit its light towards the flow stream (fig. 1, 8), which is a laser (column 7, lines 56-67 and column 8, lines 1-13). There is a second detector (fig. 1, 20 and 22) adapted to detect the second light emanating from the particle in response to the second emitted light striking the particle (column 7, 62-67). The controller is adapted to control the first light emitting device based on the detection of the second emanating light by the second detector (column 8, lines 8-17).

Claims 39-40, 42 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zarling et al. (USPN 5,674,698), newly cited, in view of Hoffman et al. (USPN 5,528,045) previously cited.

In regards to claims 39-40 and 51, Zarling discloses an apparatus for examining a particle in a flow stream of a flow cytometer as discussed above. Zarling does not disclose a light-obstructing device with two transparent portions to allow portions of the emanating light from a particle to be detected.

Hoffman discloses an apparatus for detecting particles in a flow cytometer. The particles are tagged with multiple fluorochromes, which are excited at different locations in a flow cell by different excitation sources. A light-obstructing device (fig. 1, SPF), having a substantially opaque portion and two substantially transparent portions (Fig. 1, AP1 and AP2), is placed before a detector so that the emanating light from each fluorochrome attached to the particle can be discriminated and detected separately (column 2, lines 49-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a light obstructing device with two substantially transparent portions into the combined apparatus in order to detect light from two different fluorochromes attached to a particle.

In regards to claim 42, combining a light-obstructing device with an apparatus for examining a particle in a flow stream of a flow cytometer is discussed above. Furthermore, the light-obstructing device is located at an image plane (Hoffman column 3, lines 1-5).

Response to Arguments

Applicant's arguments with respect to claims 1-4, 7-12, 14-18, and 21-51 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claim 26 is allowed over the prior art of record.

Claim 41 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Art Unit: 2877

As to claim 26, the prior art of record, taken alone or in combination, fails to disclose or render obvious an apparatus for examining a particle in a flow stream of a flow cytometer comprising a light obstructing device with two transparent portions wherein one transparent portion is larger than the other transparent portion, in combination with the rest of the limitations of claim 26.

As to claim 41, the prior art of record, taken alone or in combination, fails to disclose or render obvious an apparatus for examining a particle in a flow stream of a flow cytometer comprising a light obstructing device with two transparent portions wherein one transparent portion is larger than the other transparent portion, in combination with the rest of the limitations of claim 41.

Additional Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art made of record is Arrington (USPN 4,306,805), and McEwan (5,767,953).

Arrington teaches pulsing an LED at a duty cycle of about 10% reducing the temperature rise of the LED and increasing the light intensity during the pulse.

McEwan discloses pulsing a LED at a duty cycle of about 1% to save battery power.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 2877

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kara E Geisel whose telephone number is 703 305 7182. The examiner can normally be reached on Monday through Friday, 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Font can be reached on 703 308 4881. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872 9318 for regular communications and 703 872 9319 for After Final communications. For inquiries of a general nature, the Customer Service fax number is 703 872 9317.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1782.



F.L. Evans
Primary Examiner
Art Unit 2877



KEG
June 13, 2003